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10/598,911	06/07/2007	James William Leahy	05-905-A5	1912
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MCDONNELL BOEHNEN HULBERT @ BERGHOFF LLP			CHUNG, SUSANNAH LEE	
300 SOUTH WACKER DRIVE			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,911	Applicant(s) LEAHY ET AL.
	Examiner SUSANNAH CHUNG	Art Unit 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 July 2010.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) 13-19,22-26,38-44,47-51 and 56-61 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12,20,21,27-37,45,46 and 52-55 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No./Mail Date 9/14/06

4) Interview Summary (PTO-413)
 Paper No./Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Claims 1-61 are pending in the instant application.

Priority

This application is a 371 of PCT/US05/10969, filed 03/31/2005, which claims benefit of 60/558,800, which was abandoned and revived.

Petition under 37 C.F.R. 1.137(b)

The petition to revive the instant application under 37 C.F.R. 1.137(b), filed March 24, 2010, was granted on June 8, 2010.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 9/14/06 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Election/Restrictions

Applicant's election without traverse of Group I, claims 1-55, in the reply filed on 3/24/10 is acknowledged. The election of species is also acknowledged.

Scope of the Elected Invention

Claims 1-55 are pending in this application. Claims 13-19, 22-26, 38-44, 47-51, and 56-61 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the elected subject matter that will be examined and searched is as follows: a compound of formula (I), wherein:

R1, R2, R3, R5 and Rc are hydrogen;

R4 and R6 are optionally substituted C1-6alkyl;

X is S;

Y is =N-;

One of Z is =C(C(=O)W)-, while the other Z is =C(Rc)-;

W is -N(R5)R6; and

L is -C(=O)-.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 28 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of formula (I) or a therapeutically acceptable salt or hydrate, does not reasonably provide enablement for a **prodrug or metabolite** of those compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims recite specific compounds of structural formula (I) and the therapeutically acceptable salts of said compounds. However, the specification fails to teach the preparation of prodrugs or metabolites. Therefore, the specification is not adequately enabled for these terms.

Finding a prodrug or metabolite is an empirical exercise. Predicting if a certain ester of a claimed alcohol, for example, is in fact a prodrug or metabolite, that produces the active compound metabolically, in man, at a therapeutic concentration and at a useful rate is filled with experimental uncertainty. Although attempts have been made to predict drug metabolism *de novo*, this is still an experimental science. For a compound to be a prodrug or metabolite, it must meet three tests. It must itself be biologically inactive. It must be metabolized to a second substance in a human at a rate and to an extent to produce that second substance at a physiologically meaningful concentration. Thirdly, that second substance must be clinically effective. Determining whether a particular compound meets these three criteria in a clinical trial setting requires a large quantity of experimentation.

Prodrugs and metabolites require a significant amount of research. There is also a low expectation of success. Since, the prodrug and metabolite concept is a pharmacokinetic issue, the lack of any standard pharmacokinetic protocol discussed in the specification is relevant. Ultimately, extensive development must be undertaken to find a prodrug or metabolite.

It is not the norm that one can predict with any accuracy a particular prodrug or metabolite form of an active compound will be more soluble, more easily handled in formulations or more bioavailable without actual testing *in vivo*. The specification provides no guidance as to what types are suitable for the instantly claimed compounds.

The factors to be considered when determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, were described in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as:

1. the nature of the invention;
2. the breadth of the claims;
3. the state of the prior art;
4. the relative skill of those in the art;
5. the predictability or unpredictability of the art;
6. the amount of direction or guidance presented (by the inventor);
7. the presence or absence of working examples; and
8. the quantity of experimentation necessary (to make and/or use the invention).

The eight Wands factors are applied to the claims of the present invention below:

(1) The Nature of the Invention

The nature of the invention is the clinical use of the compounds and the pharmacokinetic behavior of substances in the human body. Prodrugs and metabolites require a significant amount of research. There is also a low expectation of success. Since, the prodrug and metabolite concept is a pharmacokinetic issue, the lack of any standard pharmacokinetic protocol discussed in the specification is relevant. Ultimately, extensive development must be undertaken to find a prodrug or metabolite.

(2) The Breadth of the claims

The breadth of claims 1, 28 and 55 encompass prodrugs, and metabolites of the compounds of formula (I). The applicable rule for interpreting the claims is that "each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description." See MPEP 2163(II)(1), citing In re Morris, 127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In view of this rule, all of the potential salts, solvates, hydrates, prodrugs, metabolites, etc... that could be formed will be interpreted to be encompassed by the instant claims.

(3) The state of the prior art

It was known in the art at the time of this application that compounds can exist in salt form.

(4) The relative skill of those in the art

The level of skill in the art (pharmaceutical chemists, physicians) would be high. Artisans making prodrugs/metabolites would require a collaborative team of synthetic pharmaceutical chemists and metabolism experts. All would have a Ph. D. degree and several years of industrial experience.

(5) The predictability or unpredictability of the art

The predictability of the art with regard to salts is known, but the preparation of prodrugs and metabolites are compound specific. In addition, the extremely large scope of the potential prodrugs and metabolites that could be produced using the compound of formula (I) renders the prior art unpredictable for making or using products as claimed on such a grand scale. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved, and

physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(6) The amount of direction or guidance presented (by the inventor)

There is no guidance in the specification drawn to prodrugs or metabolites of the instantly claimed compounds of formula (I). In addition, the specification provides no guidance as to what type(s) of prodrugs or metabolites are suitable for the instantly claimed compounds.

(7) The presence or absence of working examples

The specification has no working examples of prodrugs or metabolites of the instantly claimed compounds.

(8) The quantity of experimentation necessary (to make and/or use the invention)

The quantity of experimentation is undue given the absence of direction or guidance (or working examples) in the specification for the extremely large number of prodrugs and metabolites that could be encompassed by the claims. Identifying a prodrug or metabolite requires knowledge of the properties of the solvents and solutes and their reactions and/or transformation, nothing short of extensive testing (none identified) would be needed to determine if additional derivatives exist and thus, such as scope as literally claimed herein is non-enabled.

MPEP 2164.01(a) states, “[a] conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re*

Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to determine if any particular compound is, in fact, a prodrug or metabolite.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 20-21, 27-37, 45-46, 52, and 54-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification although enabling for a compound of Formula (I), wherein R4 is –CH2-CH2-cyclic (i.e. phenyl, aryl or heterocyclic moiety) optionally substituted and R6 is -CH2-O-phenyl optionally substituted, it is not enabled for all compounds of Formula (I), wherein R4 and R6 are optionally substituted C1-6alkyl in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), "there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

The factors to be considered when determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, were described in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as:

1. the nature of the invention;
2. the breadth of the claims;
3. the state of the prior art;
4. the relative skill of those in the art;
5. the predictability or unpredictability of the art;
6. the amount of direction or guidance presented (by the inventor);
7. the presence or absence of working examples; and
8. the quantity of experimentation necessary (to make and/or use the invention).

The eight Wands factors are applied to Claims 1-12, 20-21, 27-37, 45-46, 52, and 54-55 of the present invention below:

(1) The Nature of the Invention

The nature of the invention is a thiazole compound.

(2) The Breadth of the claims

The breadth of the claims encompasses products wherein there is no support for R4 and R6 being optionally substituted C1-6alkyl in general. The applicable rule for interpreting the claims is that "each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description."

See MPEP 2163(II)(1), citing In re Morris, 127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In view of this rule, the products of Formula (I) may reasonably be interpreted to encompass an infinite number of combinations that involve a multitude of heterocyclic and non-heterocyclic compounds.

(3) The state of the prior art

Thiazole compounds using amino acid side chains encompass a vast field. Specific support must be presented when a particular compound is being claimed. The processes of making each compound is different as is the mechanism of action. Therefore, support is always given for claimed compounds.

(4) The relative skill of those in the art

The level of skill in the art (pharmaceutical chemists, physicians) would be high.

(5) The predictability or unpredictability of the art

The compounds claimed in the instant application, wherein the variables R4 and R6 of the compound of Formula (I) are open to interpretation, include an extremely large scope of the potential products as encompassed by the claims rendering the prior art unpredictable for making or using the products as claimed on such a grand scale.

(6) The amount of direction or guidance presented (by the inventor)

The specification in the present invention discloses chemical examples of the species of Formula (I) found in claim 53. In all of the species and examples in the specification R4 is always –CH₂–CH₂-cyclic optionally substituted and R6 is –CH₂–O–phenyl optionally substituted. The process of making the instantly claimed compounds with anything other than these compounds is unpredictable.

(7) The presence or absence of working examples

The specification provides guidance for the R4 and R6 variables wherein R4 is always –CH₂–CH₂-cyclic optionally substituted and R6 is –CH₂–O-phenyl optionally substituted.

If additional examples within the elected subject matter other than the ones listed above, present please point them out.

(8) The quantity of experimentation necessary (to make and/or use the invention)

Given the absence of direction or guidance (or working examples) in the specification for any of the extremely large number of compounds that would be encompassed by the descriptions "optionally substituted C1-6alkyl," it would cause a skilled artisan an undue amount of experimentation to determine which product the process of making was describing. It is noted that the term "optionally substituted C1-6alkyl" can be substituted with anything under the sun from amino acid side chains to heterocyclic atoms and groups.

Amino acid side chains can be any amino acid side chain-from natural or nonnatural amino acids-including alpha amino acids, beta amino acids, gamma amino acids, L-amino acids, and D-amino acids. Unfortunately, the working examples provided in the instant specification do not enable the substitution of all these amino acids at the R4 or R6 positions.

Also, a skilled artisan would not be able to predict if the instantly disclosed process would work in making those additional compounds. Therefore, to overcome this rejection, the scope of the compound should be defined to those compounds with support in the specification. For example, the compounds of formula (I), wherein **R4 is -CH₂-CH₂-aryl or heterocyclyl optionally substituted and R6 is -CH₂-O-phenyl optionally substituted only.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 20-21, 27-37, 45-46, 52, and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Debono et al., J.O.C., 1992, 57(19), 5200-5208.

Applicants claims relate to compound of Formula (I) in claim 1. Debono discloses compounds that anticipate the instantly claimed genus wherein: R1, R2, R3, R5 and Rc are hydrogen; R4 and R6 are optionally substituted C1-6alkyl; X is S; Y is =N-; Z is =C(C(=O)W)-, while the other Z is =C(Rc)-; W is –N(R5)R6; and L is –C(=O)–. See Debono, page 5203, Scheme I, Compound 11, 2-[1-[[[2-[(acetylamino)methyl]-4-thiazoly]carbonyl]amino]ethyl]-4-Thiazolecarboxylic acid methyl ester, CAS RN 143346-89-8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 20-21, 27-37, 45-46, 52, and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoekstra, et al., Bioorg. Med. Chem. Lett., 1998, Vol. 8, 1649-1654.

Applicants claims relate to compound of Formula (I) in claim 1. Hoekstra discloses compounds that anticipate the instantly claimed genus wherein: **R1, R2, R3, R5 and Rc** are hydrogen; **R4 and R6** are optionally substituted C1-6alkyl; **X** is S; **Y** is =N-; **Z** is =C(C(=O)W)-, while the other **Z** is =C(Rc)-; **W** is –N(R5)R6; and **L** is –C(=O)–. See Hoekstra, page 1650, compounds 4 and 5 and page 1651, compound 11 and Table 1 showing platelet aggregation and PAR-1 binding IC50 values.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

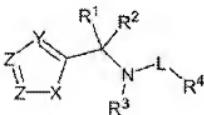
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 20-21, 27-37, 45-46, and 52-55 are rejected under 35 U.S.C. 103(a) as being obvious in view of Debono/Hoekstra et al., J.O.C., 1992, 57(19), 5200-5208 or Hoekstra, et al., Bioorg. Med. Chem. Lett., 1998, Vol. 8, 1649-1654..

Applicants claims relate to thiazole compound of Formula (I) in claim 1,



Determination of the scope and content of the prior art (MPEP § 2141.01)

Debono/Hoekstra teaches compounds that anticipate the instantly claimed genus wherein: **R1, R2, R3, R5** and **Rc** are hydrogen; **R4** and **R6** are optionally substituted C1-6alkyl; **X** is S; **Y** is =N-; **Z** is =C(C(=O)W)-, while the other **Z** is =C(Rc)-; **W** is – N(R5)R6; and **L** is –C(=O)–. See 102(b) rejection above. The Debono/Hoekstra compounds are used as antibiotics. Debono/Hoekstra uses various amino acid side chains off the thiazole compound.

Hoekstra discloses compounds that anticipate the instantly claimed genus wherein: **R1, R2, R3, R5** and **Rc** are hydrogen; **R4** and **R6** are optionally substituted C1-6alkyl; **X** is S; **Y** is =N-; **Z** is =C(C(=O)W)-, while the other **Z** is =C(Rc)-; **W** is – N(R5)R6; and **L** is –C(=O)–. See 102(b) rejection above. The Hoekstra compounds are used as thrombin receptor (PAR-1) antagonists.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Debono/Hoekstra/Hoekstra and the instant claims is that they are structural isomers, homologs, or bioisosteres of the prior art compounds.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

However, in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with Debono/Hoekstra to make the instantly claimed derivatives of a known product. The instantly claimed compounds and prior art compounds are common derivatives, such as isomers, homologs, or bioisosteres of one another.

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See MPEP 2144.09(II).

Prior art structures do not have to be true homologs or isomers to render structurally similar compounds prima facie obvious. In re Payne, 606 F.2d 303, 203 USPQ 245 (CCPA 1979) (Claimed and prior art compounds were both directed to heterocyclic carbamoyloximino compounds having pesticidal activity. The only structural difference between the claimed and prior art compounds was that the ring structures of the claimed compounds had two carbon atoms between two sulfur atoms whereas the prior art ring structures had either one or three carbon atoms between two sulfur atoms. The court held that although the prior art compounds were not true homologs or isomers of the claimed compounds, the similarity between the chemical structures and properties is sufficiently close that one of ordinary skill in the art would have been

motivated to make the claimed compounds in searching for new pesticides.). See MPEP 2144.09 (III).

Bioisosteres of compounds are well known in the art. See Patani et al., Chem Rev, 1996, Vol. 96 (8), especially page 3147. Patani teaches that there are traditional and nontraditional bioisosteres. For example, common bioisosteric replacements include substituting fluorine for hydrogen (see page 3149) or hydroxyl for amino (see page 3150). There are also nonclassical bioisosteric replacements of functional groups, such as –OH and –CH₂-OH replacements (see page 3165).

Guided by the teaching of Debono/Hoekstra one skilled in the art would be able to make similar compounds by not substituting homologs, isomers, or biosisteres off the triazole ring core or the links off the triazole ring. The motivation would be to prepare similar compounds that are pharmacologically active compounds like the compounds of Debono/Hoekstra.

The instant obviousness rejection is based on the close structural similarity of the instantly claimed compounds to the prior art compounds and the common utility shared among the compounds. There is an expectation among those of ordinary skill in the art that similar structural compounds will have similar properties and that modification of a known structure is mere experimentation within the means of a skilled artisan. See MPEP 2144.09(I). Therefore, claims 1-12, 20-21, 27-37, 45-46, and 52-55 are rejected as obvious over the prior art.

Conclusion

Claims 1-61 are pending

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Claims 1-12, 20-21, 27-37, 45-46, and 52-55 are drawn to elected subject matter.

Claims 13-19, 22-26, 38-44, 47-51, and 56-61 are drawn to nonelected subject matter.

Claims 1-12, 20-21, 27-37, 45-46, and 52-55 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Susannah Chung/
Primary Examiner, Art Unit 1626